

REMARKS/ARGUMENTS

Claim Amendments

Claim 6 has been amended due to a minor typographical error. No new matter has been added by the claim amendment herein.

REMARKS/ARGUMENTS

Claims 1-4, 8, and 9 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Patent No. 5,132,409 ("Felder") in view of DE 29609958 ("Schott Glaswerke") and in further review of U.S. Patent No. 6,200,658 ("Walther"). Reconsideration is respectfully requested.

Claims 1, 5, 6, 8, and 9 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Patent No. 5,545,396 ("Albert") in view of DE 29609958 ("Schott Glaswerke") and in further review of U.S. Patent No. 6,200,658 ("Walther"). Reconsideration is respectfully requested.

Claims 1-5, and 7-9 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Patent No. 6,466,814 ("Ardenkjaer-Larsen") in view of DE 29609958 ("Schott Glaswerke") and in further review of U.S. Patent No. 6,200,658 ("Walther"). Reconsideration is respectfully requested.

On page 4 of the Office Action dated June 29, 2007 (“Office Action”), the Examiner points out that, in a two-part claim (Jepson), the preamble acknowledges the prior art – in this case Schott Glaswerke. Applicants agree with this analysis. The Examiner goes on to assert that, in the characterizing part, “Thus, Applicant is claiming that the addition of a non-radioactive metal complex or a hyperpolarized material to the diagnostic composition is novel.” Applicants are unsure why the Examiner has focused on an analysis of the novelty of a feature of the present claims, when the issue at stake is an obviousness issue.

Moreover, the characterizing feature of a two-part Jepson claim always reads on the preamble so, in this case, the non-radioactive metal complex or a hyperpolarized material must be in the silica-coated container. Applicant’s position is in fact that a diagnostic composition which comprises a non-radioactive metal complex or a hyperpolarized material in the silica-coated containers of Schott is both novel and inventive. These compositions are not merely the results of an “addition” to the compositions of Schott – they are different to the compositions taught by Schott, because the diagnostic agent is different. The Examiner is therefore asked to withdraw the previous mischaracterizing statement.

The Examiner’s logic is apparently that, if diagnostic agents in such silica-coated containers are known, and if diagnostic agents which are non-radioactive metal complexes or hyperpolarized materials are also known, then the combination must be obvious. Applicants disagree with the Examiner’s construction. First, the Examiner’s logic amounts to finding feature A in document 1 and feature B in document 2, and asserting that the combination is inevitably obvious. This approach would probably exclude from patentability all selection

inventions or indeed claims in Jepson format. Applicants acknowledge that diagnostic agents which are either non-radioactive metal complexes or hyperpolarized materials are a subset of diagnostic agents in general. Present claim 1 can therefore be regarded as a selection invention over prior art teachings of “diagnostic agents” in general in such silica-coated containers. That is the logic for the present two-part claim format. Selection inventions have long been regarded as patentable – as long as the subset/selection brings useful benefits that could not have been anticipated by the prior art. Applicants have argued at length that diagnostic agents which are non-radioactive metal complexes or hyperpolarized materials suffer from a range of problems, which are solved by silica-coated containers. Schott teaches only solving problems for diagnostic agents which are blood and blood products. The present selection invention is therefore believed to present a useful contribution to the art, and like other selection inventions should be patentable.

Applicants wish to respectfully remind the Examiner that the required standard for establishing a *prima facie* case of obviousness falls upon the Examiner. Therefore, the evidence upon which the Examiner relies must clearly indicate that a worker of routine skill in the art would view the claimed invention as being obvious, as meant by 35 U.S.C. 103. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979).

Second, the Examiner’s logic completely ignores the issues of the suitability of the combination, and motivation to combine. It simply asserts that if the two separate components/features are known in separate prior art documents, then the combination is always obvious. Is it the Examiner’s position that ‘motivation to combine’ is irrelevant to an

obviousness analysis? Certainly it would seem that Applicant's extensive arguments on the lack of motivation to combine in the present case have been repeatedly rejected – yet the Examiner has failed to produce any real argument for motivation. Applicants would appreciate that the Examiner provide her reasoning in detail in reply to Applicant's responses. Mere reference to objections in "office actions mailed 12/29/06" being maintained is too general. Applicants need to know in detail the Examiner's reasoning as to why the (very detailed) response on each of the historic objections are maintained.

The Examiner further argues on page 5 of the Office Action that, with regard to Albert, only Example 2 teaches silicone and therefore "the teaching of the reference is not limited to silicone". Applicants agree that, any patent will have more teachings than can be found in a single Example. Applicants also agree that any reference must be considered for what it teaches the person skilled in the art read as a whole. The issue at stake here, however, is what Albert teaches about coatings – and the fact is that the only teaching of Albert on container coatings is in Example 2. Furthermore, the only coating taught by Albert in Example 2 is silicone. Hence, even if Albert is read as a whole, that key fact does not change. Consequently, the Examiner's statement is not helpful. It is therefore wholly incorrect for the Examiner to suggest that the "teachings" of Albert with respect to coatings extend to anything other than silicone. This is a matter of fact not of interpretation. Hence, if the Examiner believes that Albert does indeed teach other coatings, Applicants request that detailed page and line citations are provided. If the Examiner cannot provide such evidence, then Applicants request that the Examiner's characterization of the teaching of Albert be corrected. In the absence of such evidence, the Examiner's characterization of Albert is

clearly based on an invalid hindsight attribution of teachings which cannot be found in the reference itself. In view of these circumstances, Applicants maintain their previous arguments on Albert and request that the obviousness rejections based on Albert be withdrawn.

On page 5 of the Office Action, the Examiner also argues that an improper hindsight analysis has not been applied. Applicants concur that a proper analysis must be based on "knowledge which was within the level of ordinary skill at the time the claimed invention was made....". Applicants fail to see, however, that such a standard has been applied in this instance. The Examiner has disregarded all alternatives apart from those which lead to the subject matter of the present invention:

- (i) alternative coatings – the person skilled in the art had many coatings to choose from, all taught to have advantageous properties;
- (ii) features of Felder to improve – Felder teaches very many features, most of which are not the container are taught as being important, so the question why the vial/container would have been selected to improve is a real one;
- (iii) Albert's teaching on silicone coatings. The Examiner has consistently ignored Applicant's arguments that silicone is a very different coating, and that this disclosure of Albert therefore constitutes a teaching away. Again, the Examiner has provided no evidence or reasoning, available to the person skilled in the art at the time of the present invention, as to why this clear teaching of Albert would be ignored.

The above are important illustrations of key questions facing the person skilled in the art at the time of the claimed invention. To date, the Examiner's argumentation on (iii) is based on mischaracterization of Albert. Only very limited comments on (i) and (ii) have been provided. Disregarding the many equally plausible alternatives of (i), and the many more plausible alternatives of (ii), and failing to address the 'teaching away' issues raised by (iii) is in Applicant's view clear evidence of a hindsight analysis. Consequently, Applicants contend that the Examiner has failed to provide a convincing argument as to the motivation to combine based on the prior art of record. In the absence of such reasoning, Applicants maintain their position that an invalid hindsight analysis based on selection of features piecemeal has been applied.

Accordingly, Applicants respectfully submit that the present application, including claims 1-9, is in condition for allowance. Favorable action thereon is respectfully requested.

-Should any other matters require attention prior to allowance of the application, it is requested that the Examiner contact the undersigned.

Appl. No. 10/069,690
Amdt. Dated October 1, 2007
Reply to Office action of June 29, 2007

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.16(j) or 37 CFR 1.136(a) which may be required, or credit any overpayment, to Deposit Account No. 502-665 in the name of GE Healthcare, Inc.

Respectfully submitted,

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